

PATIENT JOURNEY CONSIDERATIONS: A Care Team Guide

INDICATION AND USAGE

TECVAYLI[®] (teclistamab-cqyv) is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

**WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGIC TOXICITY
including IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME**

Cytokine release syndrome (CRS), including life-threatening or fatal reactions, can occur in patients receiving TECVAYLI[®]. Initiate treatment with TECVAYLI[®] step-up dosing schedule to reduce risk of CRS. Withhold TECVAYLI[®] until CRS resolves or permanently discontinue based on severity.

Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) and serious, life-threatening or fatal reactions, can occur in patients receiving TECVAYLI[®]. Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment. Withhold TECVAYLI[®] until neurologic toxicity resolves or permanently discontinue based on severity.

TECVAYLI[®] is available only through a restricted program called the TECVAYLI[®] and TALVEY[®] Risk Evaluation and Mitigation Strategy (REMS).

WHAT IS TECVAYLI®?

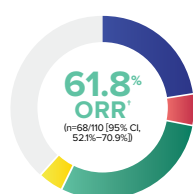
TECVAYLI® is the first bispecific BCMA × CD3 T-cell engager given as an off-the-shelf subcutaneous injection^{1,2}

Who is TECVAYLI® for?¹

TECVAYLI® is a prescription medicine that treats adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

TECVAYLI® provided clinically meaningful efficacy at a median follow-up of 7 months^{1,3}

TECVAYLI® delivered an overall response rate (ORR) of 61.8%[†]



22.7% sCR (n=25/110)

5.5% CR (n=6/110)

29.1% VGPR (n=32/110)

4.5% PR (n=5/110)

The efficacy of TECVAYLI® was evaluated in 110 patients with relapsed or refractory multiple myeloma in the single-arm, open-label, multi-center, phase 1/2 MajesTEC-1 trial. Patients had received at least 3 therapies, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. The primary endpoint was ORR and key secondary endpoints included DOR and TTR.

PRIMARY ANALYSIS

% PATIENTS ≥CR	MEDIAN TIME TO FIRST RESPONSE	MEDIAN DURATION OF RESPONSE
28.2% ≥CR [‡] (n=31/110)	1.2 months (range: 0.2–5.5 months)	Median DOR not yet reached (DOR: 9.0 months; not estimable; 95% CI)

You are now viewing a subsequent follow-up analysis of the MajesTEC-1 trial. This information is not included in the current full Prescribing Information.

At the time of the follow-up report, 25/110 (22.7%) of subjects were still on treatment.³

FINAL ANALYSIS^{3,4§}

% PATIENTS ≥CR [†]	MEDIAN TIME TO ≥CR [†]
46.4% ≥CR [‡] (n=51/110)	6.0 months (Range: 1.7-18.5 months)

• 61.8% ORR^{††} (n=68/110 [95% CI, 52.1%–70.9%])
• 46.4% (n=51/110) ≥CR[†]

• 8.2% (n=9/110) CR
• 58.2% (n=64/110) ≥VGPR[†]
• 38.2% (n=42/110) sCR

• 11.8% (n=13/110) VGPR
• 3.6% (n=4/110) PR

BCMA, B-cell maturation antigen; CD3, cluster of differentiation 3; CD38, cluster of differentiation 38; CI, confidence interval; CR, complete response; DOR, duration of response; NE, not estimable; PR, partial response; sCR, stringent complete response; TTR, time to response; VGPR, very good partial response.

*Efficacy results were based on ORR as determined by the Independent Review Committee (IRC) assessment using International Myeloma Working Group (IMWG) 2016 criteria.

[†]ORR: sCR+CR+VGPR+PR.

[‡]≥CR: sCR+CR.

[§]Based on a median duration of follow-up of 29.9 months.³

^{||}≥VGPR: sCR+CR+VGPR.

MajesTEC-1 final safety analysis information at a median follow-up of 30.4 months^{1,3,4}

At the time of the follow-up report, 38/165 (23%) of subjects were still on treatment.

Reported since end of primary analysis:

- One patient experienced 2 recurrent CRS events after a treatment delay
- No additional events of ICANS

Reported since study initiation:

- Eight treatment-related deaths occurred (4 due to COVID-19)
- Treatment-emergent adverse reactions of note (n [%] Any Grade and Grade 3/4, respectively) included: neutropenia (118 [71.5] and 108 [65.5]); infections (130 [78.8] and 91 [55.2]); and hypogammaglobulinemia (36 [21.8] and 3 [1.8])
- Permanent discontinuation of TECVAYLI® due to adverse reactions occurred in 5.5% of patients
 - Adverse Reactions resulting in permanent discontinuation of TECVAYLI® were COVID-19 in 2 patients; progressive multifocal leukoencephalopathy, sepsis, arthralgia, polyarthritis, and brain neoplasm in 1 patient each; and events of pneumocystis jirovecii pneumonia and pneumonia adenoviral in the same patient, and hypercalcemia

Please read full Important Safety Information on pages 8-12, and full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

GETTING PATIENTS STARTED

PRETREATMENT MEDICATIONS¹



Prior to starting treatment with TECVAYLI®

Consider initiation of antiviral prophylaxis to prevent herpes zoster reactivation per local institutional guidelines. Monitor patients for signs and symptoms of infection prior to and during treatment with TECVAYLI® and treat appropriately. Verify pregnancy status of females of reproductive potential prior to initiating TECVAYLI®. Because of the potential for serious adverse reactions in a breastfed child, advise patients not to breastfeed during treatment with TECVAYLI® and for 5 months after the last dose.



1 to 3 hours before dose

Administer the following pretreatment medications 1 to 3 hours before each dose of the TECVAYLI® step-up dosing schedule, which includes step-up dose 1, step-up dose 2, and the first treatment dose, to reduce the risk of CRS:

- Corticosteroid (oral or intravenous dexamethasone 16 mg)
- Histamine-1(H1) receptor antagonist (oral or intravenous diphenhydramine 50 mg or equivalent)
- Antipyretics (oral or intravenous acetaminophen 650 mg to 1,000 mg or equivalent)



Prior to administration of weekly doses

Administration of pretreatment medications may be required prior to administration of subsequent doses of TECVAYLI® in the following patients:

- Patients who repeat doses within the step-up dosing schedule following a dose delay
- Patients who experienced CRS following the prior dose of TECVAYLI®

Monitor patients for signs and symptoms of infection prior to and during treatment with TECVAYLI® and treat appropriately.

Prescribers must be certified to treat with TECVAYLI®; pharmacies and healthcare settings must be enrolled to dispense TECVAYLI®.

**Encourage your patients to carry the
TECVAYLI® and TALVEY® REMS Patient Wallet Card
with them at all times.**

Download the [Dosing and Adverse Reaction Management Pocket Guide](#) for more information about preparing, storing, and adverse reaction management for TECVAYLI®.

CRS, cytokine-release syndrome; REMS, Risk Evaluation and Mitigation Strategy.

IMPORTANT SAFETY INFORMATION (continued) WARNINGS AND PRECAUTIONS (continued)

Cytokine Release Syndrome - TECVAYLI® can cause cytokine release syndrome (CRS), including life-threatening or fatal reactions. In the clinical trial, CRS occurred in 72% of patients who received TECVAYLI® at the recommended dose, with Grade 1 CRS occurring in 50% of patients, Grade 2 in 21%, and Grade 3 in 0.6%. Recurrent CRS occurred in 33% of patients. Most patients experienced CRS following step-up dose 1 (42%), step-up dose 2 (35%), or the initial treatment dose (24%). Less than 3% of patients developed first occurrence of CRS following subsequent doses of TECVAYLI®. The median time to onset of CRS was 2 (range: 1 to 6) days after the most recent dose with a median duration of 2 (range: 1 to 9) days. Clinical signs and symptoms of CRS included, but were not limited to, fever, hypoxia, chills, hypotension, sinus tachycardia, headache, and elevated liver enzymes (aspartate aminotransferase and alanine aminotransferase elevation).

Initiate therapy according to TECVAYLI® step-up dosing schedule to reduce risk of CRS. Administer pretreatment medications to reduce risk of CRS and monitor patients following administration of TECVAYLI® accordingly. At the first sign of CRS, immediately evaluate patient for hospitalization. Administer supportive care based on severity and consider further management per current practice guidelines. Withhold or permanently discontinue TECVAYLI® based on severity.

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A SUBCUTANEOUS INJECTION WITH AN ADAPTIVE STEP-UP DOSING SCHEDULE AND PERSONALIZED WEIGHT-BASED DOSING¹

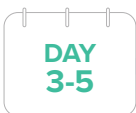
STEP-UP DOSES

Step-up dose 1
(0.06 mg/kg)



Minimum of
2 DAYS

Step-up dose 2
(0.3 mg/kg)



Minimum of
2 DAYS

First treatment dose
(1.5 mg/kg)



Step-up dose 2 may be given between 2 to 4 days after step-up dose 1 and may be given up to 7 days after step-up dose 1 to allow for resolution of adverse reactions

First treatment dose may be given between 2 to 4 days after step-up dose 2 and may be given up to 7 days after step-up dose 2 to allow for resolution of adverse reactions

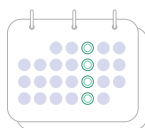
Due to the risk of CRS and neurologic toxicity, including ICANS, patients should be hospitalized for 48 hours after administration of all doses within the TECVAYLI® step-up dosing schedule.

FOLLOWING STEP-UP DOSING ONGOING WEEKLY DOSING BEGINS, FOLLOWED BY A BIWEEKLY (Q2W) TREATMENT OPTION FOR CERTAIN PATIENTS¹

ONGOING DOSING WITH TECVAYLI®

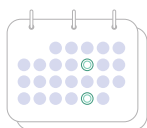
After step-up dosing, patients will receive weekly treatment doses with the option of switching to biweekly (Q2W) dosing if they achieve and maintain $\geq$ CR* for a minimum of 6 months

Weekly treatment doses
(1.5 mg/kg)



Weekly Dosing: Once-weekly dosing until disease progression or unacceptable toxicity

Biweekly (Q2W) treatment doses
(1.5 mg/kg)



Biweekly (Q2W) Dosing Option: Extended dosing interval beyond 6 months. The dosing frequency may be decreased to once every 2 weeks after $\geq$ 6 months of achieving and maintaining $\geq$ CR* during treatment until disease progression or unacceptable toxicity

* $\geq$ CR: sCR+CR.

Remember: Dose is personalized to each patient's actual body weight. Please refer to Tables 7-9 in the full Prescribing Information to determine the dosage based on predetermined weight ranges. Dose reductions are not recommended, and dose delays may be required to manage toxicities.

TECVAYLI® is administered by a healthcare provider according to the step-up dosing schedule to reduce the incidence and severity of CRS.

Share the [TECVAYLI® Patient Brochure](#) with your patients so they can learn more about TECVAYLI® and discover patient resources.

ICANS, immune effector cell-associated neurotoxicity syndrome; Q2W, every 2 weeks.

IMPORTANT SAFETY INFORMATION (continued) WARNINGS AND PRECAUTIONS (continued)

Neurologic Toxicity including ICANS - TECVAYLI® can cause serious, life-threatening or fatal neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS).

In the clinical trial, neurologic toxicity occurred in 57% of patients who received TECVAYLI® at the recommended dose, with Grade 3 or 4 neurologic toxicity occurring in 2.4% of patients. The most frequent neurologic toxicities were headache (25%), motor dysfunction (16%), sensory neuropathy (15%), and encephalopathy (13%). With longer follow-up, Grade 4 seizure and fatal Guillain-Barré syndrome (one patient each) occurred in patients who received TECVAYLI®.

In the clinical trial, ICANS was reported in 6% of patients who received TECVAYLI® at the recommended dose. Recurrent ICANS occurred in 1.8% of patients. Most patients experienced ICANS following step-up dose 1 (1.2%), step-up dose 2 (0.6%), or the initial treatment dose (1.8%). Less than 3% of patients developed first occurrence of ICANS following subsequent doses of TECVAYLI®.

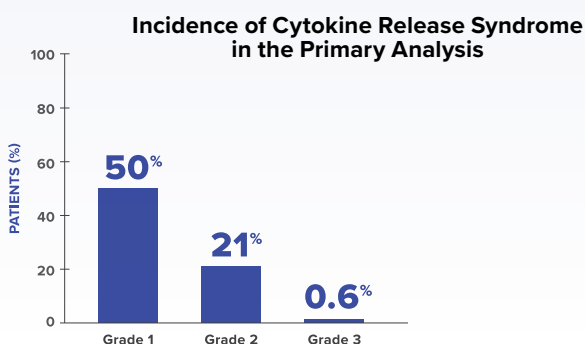
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WHAT TO LOOK FOR: CRS, NEUROLOGICAL TOXICITY INCLUDING ICANS, AND INFECTIONS

CRS

CRS, including life-threatening or fatal reactions, may occur in patients receiving TECVAYLI®¹

CRS of any grade was reported in 72% of patients receiving TECVAYLI® in the primary analysis



If not already hospitalized, at the first sign of CRS, immediately evaluate patient for hospitalization. Administer supportive care based on severity and consider further management per current practice guidelines. Withhold or permanently discontinue TECVAYLI® based on severity.

TECVAYLI® is available only through a restricted program under a REMS.

NEUROLOGIC TOXICITY, INCLUDING ICANS

Serious or life-threatening neurologic toxicities, including ICANS, may occur following treatment with TECVAYLI®¹

In the primary analysis, neurologic toxicities were reported in 57% of patients receiving TECVAYLI® at the recommended dose.

- The most frequent neurologic toxicities were headache (25%), motor dysfunction (16%), sensory neuropathy (15%), and encephalopathy (13%)
- With longer follow-up, 1 patient experienced Grade 4 seizure and 1 patient experienced fatal Guillain-Barré syndrome
- Grade 3 and Grade 4 neurologic toxicity events (2.4%) have been observed in patients treated with TECVAYLI®

Monitor patients for signs and symptoms of neurologic toxicity during treatment. At the first sign of neurologic toxicity, including ICANS, immediately evaluate patient and provide supportive therapy based on severity.

Continued on next page >>>

CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome.

IMPORTANT SAFETY INFORMATION (continued) WARNINGS AND PRECAUTIONS (continued)

Neurologic Toxicity including ICANS (continued) - The median time to onset of ICANS was 4 (range: 2 to 8) days after the most recent dose with a median duration of 3 (range: 1 to 20) days. The most frequent clinical manifestations of ICANS reported were confusional state and dysgraphia. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS.

Monitor patients for signs and symptoms of neurologic toxicity during treatment. At the first sign of neurologic toxicity, including ICANS, immediately evaluate patient and provide supportive therapy based on severity. Withhold or permanently discontinue TECVAYLI® based on severity per recommendations and consider further management per current practice guidelines.

Due to the potential for neurologic toxicity, patients are at risk of depressed level of consciousness. Advise patients to refrain from driving or operating heavy or potentially dangerous machinery during and for 48 hours after completion of TECVAYLI® step-up dosing schedule and in the event of new onset of any neurologic toxicity symptoms until neurologic toxicity resolves.

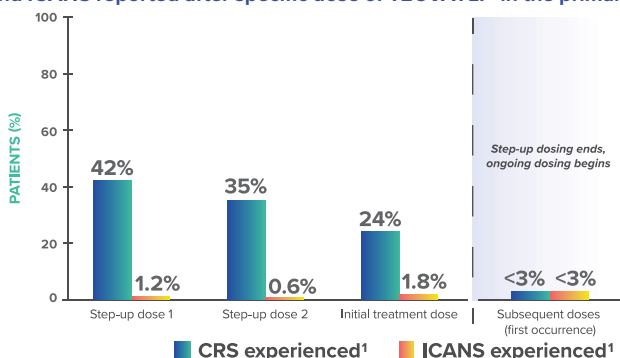
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TECVAYLI® and TALVEY® REMS - TECVAYLI® is available only through a restricted program under a REMS called the TECVAYLI® and TALVEY® REMS because of the risks of CRS and neurologic toxicity, including ICANS.

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NEUROLOGIC TOXICITY, INCLUDING ICANS (CONTINUED)

CRS and ICANS reported after specific dose of TECVAYLI® in the primary analysis¹



Median time to onset:

2 days (range: 1-6) after most recent dose

Median duration: 2 days (range: 1-9)

- Recurrent CRS occurred in 33% of patients

If not already hospitalized, at the first sign of CRS, immediately evaluate patient for hospitalization.

Administer supportive care based on severity and consider further management per current practice guidelines. Withhold or permanently discontinue TECVAYLI® based on severity.

Median time to onset:

4 days (range: 2-8) after most recent dose

Median duration: 3 days (range: 1-20)

The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS.

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INFECTIONS

TECVAYLI® can cause severe, life-threatening, or fatal reactions. In the primary analysis, serious infections, including opportunistic infections, occurred in 30% of patients receiving TECVAYLI® at the recommended dose¹

- Grade 3 or 4 infections occurred in 35% and fatal infections in 4.2%
- Monitor patients for signs and symptoms of infection prior to and during treatment with TECVAYLI® and treat appropriately. Administer prophylactic antimicrobials according to guidelines
- Withhold TECVAYLI® or consider permanent discontinuation of TECVAYLI® based on severity
- Monitor immunoglobulin levels during treatment with TECVAYLI® and treat according to guidelines, including infection precautions and antibiotic or antiviral prophylaxis

CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome.

IMPORTANT SAFETY INFORMATION (continued) WARNINGS AND PRECAUTIONS (continued)

Hepatotoxicity - TECVAYLI® can cause hepatotoxicity, including fatalities. In patients who received TECVAYLI® at the recommended dose in the clinical trial, there was one fatal case of hepatic failure. Elevated aspartate aminotransferase (AST) occurred in 34% of patients, with Grade 3 or 4 elevations in 1.2%. Elevated alanine aminotransferase (ALT) occurred in 28% of patients, with Grade 3 or 4 elevations in 1.8%. Elevated total bilirubin occurred in 6% of patients with Grade 3 or 4 elevations in 0.6%. Liver enzyme elevation can occur with or without concurrent CRS.

Monitor liver enzymes and bilirubin at baseline and during treatment as clinically indicated. Withhold TECVAYLI® or consider permanent discontinuation of TECVAYLI® based on severity.

TAKING THE NEXT STEP

TRANSITION OF CARE

In the event that a patient continues treatment in another center, you may need to coordinate care with the other center to ensure a smooth transition of care

When counseling patients on transition of care:

- Communicate and outline the step-up dosing schedule and administrative logistics to patients and their caregivers
- Ensure that the patient has support during treatment, including transportation to and from each appointment if needed
- Ensure the patient knows the next scheduled treatment dose
- Ensure patient has support materials, such as brochures and other resources

SUPPORT AND RESOURCES

Once you have made the clinical decision to prescribe TECVAYLI®, Johnson & Johnson has resources to help you support your patients.



J&J withMe is your single source for access, affordability, and treatment support programs from Johnson & Johnson. Your patients will be connected to TECVAYLI withMe.

- **Access Support**—to help navigate payer processes
- **Affordability Resources**—to help patients discover ways to afford their TECVAYLI® medicine
- **Personalized, free 1-on-1 Care Navigator Support for Your Patients**—offered through TECVAYLI withMe to support the nonclinical needs that may arise while on TECVAYLI®

Get started with J&J withMe

- Visit Portal.JNJwithMe.com to investigate insurance coverage for your patients, enroll your patients in savings, or sign them up for Care Navigator support
- Visit JNJwithMe.com/hcp/TECVAYLI for access and affordability information for the J&J medicine you prescribed
- Bookmark these links for quick and easy access!
- Call [833-JNJ-wMe1 \(833-565-9631\)](tel:833-JNJ-wMe1), Monday through Friday, 8:00 AM to 8:00 PM ET

The patient support and resources provided by J&J withMe are not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, provide case management services, or serve as a reason to prescribe TECVAYLI®.

Learn more about the support available to you and your patients at TecvayliHCP.com/support-and-resources

IMPORTANT SAFETY INFORMATION (continued) WARNINGS AND PRECAUTIONS (continued)

Infections - TECVAYLI® can cause severe, life-threatening, or fatal infections. In patients who received TECVAYLI® at the recommended dose in the clinical trial, serious infections, including opportunistic infections, occurred in 30% of patients, with Grade 3 or 4 infections in 35%, and fatal infections in 4.2%. Monitor patients for signs and symptoms of infection prior to and during treatment with TECVAYLI® and treat appropriately. Administer prophylactic antimicrobials according to guidelines. Withhold TECVAYLI® or consider permanent discontinuation of TECVAYLI® based on severity.

Monitor immunoglobulin levels during treatment with TECVAYLI® and treat according to guidelines, including infection precautions and antibiotic or antiviral prophylaxis.

Neutropenia - TECVAYLI® can cause neutropenia and febrile neutropenia. In patients who received TECVAYLI® at the recommended dose in the clinical trial, decreased neutrophils occurred in 84% of patients, with Grade 3 or 4 decreased neutrophils in 56%. Febrile neutropenia occurred in 3% of patients.

Monitor complete blood cell counts at baseline and periodically during treatment and provide supportive care per local institutional guidelines. Monitor patients with neutropenia for signs of infection. Withhold TECVAYLI® based on severity.

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Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) and serious, life-threatening or fatal reactions, can occur in patients receiving TECVAYLI®. Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment. Withhold TECVAYLI® until neurologic toxicity resolves or permanently discontinue based on severity.

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IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

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Initiate therapy according to TECVAYLI® step-up dosing schedule to reduce risk of CRS. Administer pretreatment medications to reduce risk of CRS and monitor patients following administration of TECVAYLI® accordingly. At the first sign of CRS, immediately evaluate patient for hospitalization. Administer supportive care based on severity and consider further management per current practice guidelines. Withhold or permanently discontinue TECVAYLI® based on severity.

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Neurologic Toxicity including ICANS - TECVAYLI® can cause serious, life-threatening or fatal neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS).

In the clinical trial, neurologic toxicity occurred in 57% of patients who received TECVAYLI® at the recommended dose, with Grade 3 or 4 neurologic toxicity occurring in 2.4% of patients. The most frequent neurologic toxicities were headache (25%), motor dysfunction (16%), sensory neuropathy (15%), and encephalopathy (13%). With longer follow-up, Grade 4 seizure and fatal Guillain-Barré syndrome (one patient each) occurred in patients who received TECVAYLI®.

In the clinical trial, ICANS was reported in 6% of patients who received TECVAYLI® at the recommended dose. Recurrent ICANS occurred in 1.8% of patients.

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IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Neurologic Toxicity including ICANS (continued) - Most patients experienced ICANS following step-up dose 1 (1.2%), step-up dose 2 (0.6%), or the initial treatment dose (1.8%). Less than 3% of patients developed first occurrence of ICANS following subsequent doses of TECVAYLI®. The median time to onset of ICANS was 4 (range: 2 to 8) days after the most recent dose with a median duration of 3 (range: 1 to 20) days. The most frequent clinical manifestations of ICANS reported were confusional state and dysgraphia. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS.

Monitor patients for signs and symptoms of neurologic toxicity during treatment. At the first sign of neurologic toxicity, including ICANS, immediately evaluate patient and provide supportive therapy based on severity. Withhold or permanently discontinue TECVAYLI® based on severity per recommendations and consider further management per current practice guidelines.

Due to the potential for neurologic toxicity, patients are at risk of depressed level of consciousness. Advise patients to refrain from driving or operating heavy or potentially dangerous machinery during and for 48 hours after completion of TECVAYLI® step-up dosing schedule and in the event of new onset of any neurologic toxicity symptoms until neurologic toxicity resolves.

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Monitor liver enzymes and bilirubin at baseline and during treatment as clinically indicated. Withhold TECVAYLI® or

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IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Hepatotoxicity (continued) - consider permanent discontinuation of TECVAYLI® based on severity.

Infections - TECVAYLI® can cause severe, life-threatening, or fatal infections. In patients who received TECVAYLI® at the recommended dose in the clinical trial, serious infections, including opportunistic infections, occurred in 30% of patients, with Grade 3 or 4 infections in 35%, and fatal infections in 4.2%. Monitor patients for signs and symptoms of infection prior to and during treatment with TECVAYLI® and treat appropriately. Administer prophylactic antimicrobials according to guidelines. Withhold TECVAYLI® or consider permanent discontinuation of TECVAYLI® based on severity.

Monitor immunoglobulin levels during treatment with TECVAYLI® and treat according to guidelines, including infection precautions and antibiotic or antiviral prophylaxis.

Neutropenia - TECVAYLI® can cause neutropenia and febrile neutropenia. In patients who received TECVAYLI® at the recommended dose in the clinical trial, decreased neutrophils occurred in 84% of patients, with Grade 3 or 4 decreased neutrophils in 56%. Febrile neutropenia occurred in 3% of patients.

Monitor complete blood cell counts at baseline and periodically during treatment and provide supportive care per local institutional guidelines. Monitor patients with neutropenia for signs of infection. Withhold TECVAYLI® based on severity.

Hypersensitivity and Other Administration Reactions - TECVAYLI® can cause both systemic administration-related and local injection-site reactions. Systemic Reactions - In patients who received TECVAYLI® at the recommended dose in the clinical trial, 1.2% of patients experienced systemic-administration reactions, which included Grade 1 recurrent pyrexia and Grade 1 swollen tongue. Local Reactions - In patients who received TECVAYLI® at the recommended dose in the clinical trial, injection-site reactions occurred in 35% of patients, with Grade 1 injection-site reactions in 30% and Grade 2 in 4.8%. Withhold TECVAYLI® or consider permanent discontinuation of TECVAYLI® based on severity.

Embryo-Fetal Toxicity - Based on its mechanism of action, TECVAYLI® may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with TECVAYLI® and for 5 months after the last dose.

Please read additional Important Safety Information on following page, and full [Prescribing Information](#), including Boxed WARNING, for TECVAYLI®.

IMPORTANT SAFETY INFORMATION (continued)
ADVERSE REACTIONS

The most common adverse reactions ($\geq 20\%$) were pyrexia, CRS, musculoskeletal pain, injection site reaction, fatigue, upper respiratory tract infection, nausea, headache, pneumonia, and diarrhea. The most common Grade 3 to 4 laboratory abnormalities ($\geq 20\%$) were decreased lymphocytes, decreased neutrophils, decreased white blood cells, decreased hemoglobin, and decreased platelets.

Please read full [Prescribing Information](#), including **Boxed WARNING**, for **TECVAYLI®**.

cp-322928v5

References: **1.** TECVAYLI® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** U.S. Food and Drug Administration. FDA approves teclistamab-cqyv for relapsed or refractory multiple myeloma. Accessed May 1, 2025. <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-teclistamab-cqyv-relapsed-or-refractory-multiple-myeloma> **3.** Data on file. Janssen Biotech, Inc. **4.** Garfall AL, Nooka AK, van de Donk NWCJ, et al. Long-term follow-up from the phase 1/2 MajesTEC-1 trial of teclistamab in patients with relapsed/refractory multiple myeloma. Poster. Presented at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting; May 31-June 4, 2024; Chicago, IL.

Please read full Important Safety Information on pages 8-12, and full [Prescribing Information](#), including **Boxed WARNING**, for **TECVAYLI®**.